DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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SOLICITOR

APR - 3 1989

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U S PATENT & TRADEMARK OFFICE

Re: Hismanal
Docket No. 89E-0085

The Honorable Donald J. Quigg
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Quigg:

This is in regard to the application for patent term extension for U.S. Patent No. 4,219,559, filed by Janssen Pharmaceutica N.V. under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Hismanal, the human drug product claimed by the patent.

The total length of the review period for Hismanal is 2,983 days. Of this time, 1,579 days occurred during the testing phase and 1,404 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 31, 1980.

   FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was October 31, 1980.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: February 25, 1985.

   FDA has verified the applicant's claim that the date the new drug application (NDA 19-402) was initially submitted to the FDA was on February 25, 1985.

3. The date the application was approved: December 29, 1988.

   FDA has verified the applicant's claim that NDA 19-402 was approved on December 29, 1988.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Robert L. Minier
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